

REMARKS

Claims 122 and 124-137 have been canceled without prejudice to resubmission. Claims 153-167 have been amended. Upon entry of this amendment, claims 153-167 will be pending in the present application.

The renumbering of claims 61-75 as claims 153-167 is acknowledged. Claims 154 and 157-167 have been amended to correct the dependencies of these claims, based on the renumbering of these claims. Claims 155-156 have been amended to change the dependency of these claims to depend from claim 154.

Claim 153 has been amended to recite the methods of administration employed to administer the sugar cane extract. Basis for this amendment is found at page 29, lines 13-18 of the original application. Claim 153 has also been amended to require administration of an effective amount of the composition. Basis for this amendment is found at page 29, lines 5-12 of the application. Claim 153 has also been amended to require that the composition be administered to prevent occurrence of a symptom of an infection. Basis for this amendment is found in Examples 1-4 of the application as originally filed, since these examples show that the composition of the present invention is effective to remedy a disease, as indicated by the lower fatality rate of the treated mice. When a composition remedies a disease, it is commonly understood that it also prevents the appearance of a symptom after infection with the disease.

Claims 153-167 have been objected to under 37 C.F.R. §1.75 as being a substantial duplicate of claims 122 and 124-137. Although the applicant does not agree with the Examiner's position, claims 122 and 124-137 have been canceled for the purpose of obviating this objection.

Claims 124, 126, 154 and 156 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 124 and 126 have been canceled without prejudice to resubmission thereby obviating this rejection with respect to claims 124 and 126.

Claim 154 has been amended to clarify that the extract is a fraction treated by column chromatography wherein a column used in the column chromatography is packed with a fixed carrier. It is considered that this amendment overcomes the rejection of claim 154 because it clarifies that the extract is treated with a fixed carrier as part of the column chromatography.

Claim 156 has been amended to delete the reference to "out of fractions." It is considered that this amendment clarifies that claim 156 claims a specific fraction that absorbs light of a wavelength of 420 nm obtained by column chromatographic treatment utilizing

differences in affinity for an ion exchange resin packed in a column as the fixed carrier. Favorable consideration and withdrawal of the rejection in view of this amendment is requested.

Claims 122 and 153 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent no. 5,965,616 (Wang et al.). Claim 122 has been canceled without prejudice to resubmission thereby obviating the rejection of claim 122. This rejection, at least insofar as it applies to claim 153, as amended, is respectfully traversed and reconsideration is requested for the reasons which follow.

The present invention, as claimed in amended claim 153, relates to a method for preventing the appearance of a symptom after infection or a method of remedying a disease caused by an infection in humans or animals. As such, the present method, requires administration of a sugar cane-derived extract as an active ingredient to an infected human or animal, or to a human or animal having a disease caused by an infection, by a method of administration selected from the group consisting of oral, intravenous, intramuscular, subcutaneous, intracutaneous, intra-abdominal, intrarectal, hypoglossal, and instillation. Also, claim 153 requires that the infection be a bacterial infection, viral infection, or a fungal infection.

Wang teaches a method for treating skin conditions by administering to a mammal, an  $\alpha$ -hydroxyacid derived from sugar cane. Wang teaches topical administration of the composition.

As a result of the amendments to claim 153, claim 153 is novel over Wang for at least two different reasons, namely,

1. Wang does not teach or suggest administration of a sugar cane extract to a human or animal infected with a bacterial, viral or fungal infection or having a disease caused by such an infection, as is now required by claim 153, and
2. Wang does not teach or suggest any of the methods of administration which are now required by claim 153, since claim 153 does not include topical administration as disclosed in Wang.

Accordingly, for these reasons, it is considered that claim 153, as amended, is clearly novel over Wang. Favorable consideration and withdrawal of the rejection are requested.

Claims 122, 124-128, 130, 133-137, 153-158, 160 and 163-167 have been rejected under 35 U.S.C. §102(a) as being anticipated by European published patent application no. EP 0 943 343 A1 (Kawai et al.). Claims 122, 124-128, 130 and 133-137 have been canceled without prejudice to resubmission thereby obviating the rejection of these claims. The rejection, at least

insofar as it applies to claims 153-158, 160, and 163-167, as amended, is respectfully traversed and reconsideration is requested for the reasons which follow.

Kawai et al. teaches methods of administration of sugar cane extracts to humans and dogs in Examples 4-5 of Kawai et al. for the purpose of preventing or reducing odor. In each case, the compositions were orally administered to humans and dogs.

The present invention, as claimed in amended claim 153, is clearly novel over Kawai et al. since amended claim 153 now requires administration of a sugar cane extract to a human or animal infected with a bacterial, viral or fungal infection or having a disease caused by such an infection. Kawai et al. contains no teaching or suggestion to administer a sugar cane extract to an infected human or animal or to a human or animal having a disease caused by an infection, nor would a skilled person be led to administer a sugar cane extract to an infected or diseased human or animal by the teachings of Kawai et al. since Kawai et al. does not teach or suggest any beneficial effect that would be obtained which is related to the treatment of a disease caused by an infection or the prevention of an occurrence of a symptom of an infection. Accordingly, for these reasons, it is considered that claim 153, as amended, is clearly novel over Kawai et al. Claims 154-158, 160 and 163-167 all depend from claim 153 and thus are considered to be novel over Kawai et al. for at least the same reasons as given above for claim 153. Favorable consideration and withdrawal of the rejection of claims 153-158, 160, and 163-167 under 35 U.S.C. §102(a) over Kawai et al. is requested.

Claims 122, 124-137 and 153-167 have been rejected under 35 U.S.C. §103(a) as being obvious over Kawai et al., in view of U.S. Patent no. 5,443,650 (Saska), U.S. Patent no. 5,788,812 (Agar et al.), U.S. Patent no. 5,454,952 (Brewer) and U.S. Patent no. 5,102,553 (Kearney). Claims 122 and 124-137 have been canceled without prejudice to resubmission thereby obviating the rejection of these claims. This rejection, at least insofar as it applies to claims 153-167, as amended, is respectfully traversed and reconsideration is requested for the reasons which follow.

Kawai discloses a method wherein sugar cane extracts are administered to human or animal subjects, as seen from Examples 4-5, relied on by the Examiner, for the purpose of providing a deodorizing effect. The sugar cane extract can be used in foods, feeds, and medicines.

Saska discloses a method for softening an aqueous sugar juice for improved recovery of the sugars contained in the juice. A strong cation exchange resin is used for the softening and resultant improved recovery of sugars, as seen in column 2, lines 21-33.

Agar et al. discloses a method for the recovery of lignin and by-products from pulping of fibrous material, as seen in column 2, lines 66-67. More specifically, Agar et al. discloses a method for obtaining a novel lignin, a novel low molecular weight lignin, and purified furfural, as discussed in column 3, lines 22-41. The fibrous plant materials are preheated with low-pressure steam, and contacted with the twice-employed mixture of 60% ethanol and 40% water, as mentioned by the Examiner. The resulting extract or "black liquor" contains lignin, hemicellulose, other saccharides and extractives, as discussed in column 4, lines 24-45 of Saska.

Brewer discloses a method for at least partially removing inorganic ions from a sugar solution containing the ions, as can be seen from column 3, lines 31-34. For this purpose, Brewer employs an ion exchange process using strongly acidic ion exchange resins or cation exchange resins in their sodium form, as well as electrodialysis, as mentioned by the Examiner.

Kearney discloses simulated moving bed technology with ion exchange resins in column 1, lines 30-51, as mentioned by the Examiner. However, this technique is employed for the separation of sucrose from sugar cane.

The present invention, as claimed in amended claim 153, is clearly novel over Kawai et al. since amended claim 153 now requires administration of a sugar cane extract to a human or animal infected with a bacterial, viral or fungal infection or having a disease caused by such an infection. Kawai et al. contains no teaching or suggestion to administer a sugar cane extract to an infected or diseased human or animal, as discussed above, nor would a skilled person be led to administer a sugar cane extract to an infected or diseased human or animal by the teachings of Kawai et al. since Kawai et al. does not teach or suggest any beneficial effect of such administration which is related to the treatment of a disease caused by an infection or the prevention of an occurrence of a symptom of an infection.

None of Saska, Agar et al., Brewer or Kearney teaches or suggests the administration of a sugar cane extract to a human or animal infected with a bacterial, viral or fungal infection or having a disease caused by such an infection. Also, none of Saska, Agar et al., Brewer or Kearney teaches or suggests any beneficial effect related to the treatment of a disease caused by an infection or the prevention of an occurrence of a symptom of an infection. Thus, there is no

motivation in any of Kawai et al., Saska, Agar et al., Brewer or Kearney to administer a sugar cane extract to an infected or diseased human or animal, nor is there any disclosure in these references that would provide a skilled person with an expectation of successful treatment of a disease caused by an infection or prevention of a symptom of such infection, by such administration.

Finally, claim 153 has been amended to require administration of an effective amount of the sugar cane extract to prevent appearance of a symptom after infection or remedy a disease caused by infection. None of the cited references teaches or suggests that a sugar cane extract would be effective for these purposes, nor do the cited references contain any teaching as to what amount would be effective to achieve these purposes. Moreover, the disclosures of these references provide no indication that administration of the sugar cane extract was effective for either of these purposes. Thus, for these additional reasons, the subject matter of claim 153 is considered to be unobvious over the cited references.

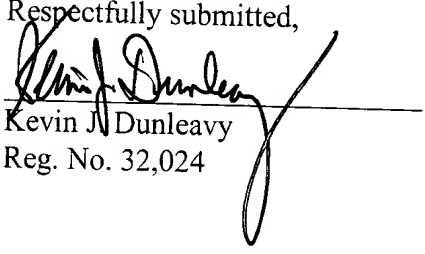
Accordingly, for these reasons, it is considered that claim 153, as amended, is clearly unobvious over Kawai et al., taken in combination with Saska, Agar et al., Brewer and Kearney. Claims 154-167 all depend from claim 153 and thus are considered to be unobvious over Kawai et al., taken in combination with Saska, Agar et al., Brewer and Kearney for at least the same reasons as given above for claim 153. Favorable consideration and withdrawal of the rejection of claims 153-167 over Kawai et al. taken in combination with Saska, Agar et al., Brewer and Kearney, is requested.

Favorable consideration and issuance of a Notice of Allowance are solicited. Should the Examiner have any questions she is encouraged to call the Applicant's representative listed below.

Dated: August 22, 2003

KNOBLE & YOSHIDA LLC  
Customer no.: 21,302  
Eight Penn Center, Suite 1350  
1628 John F. Kennedy Blvd.  
Philadelphia, PA 19103  
Phone: (215) 599-0600  
Fax: (215) 499-0601

Respectfully submitted,

  
Kevin J. Dunleavy  
Reg. No. 32,024